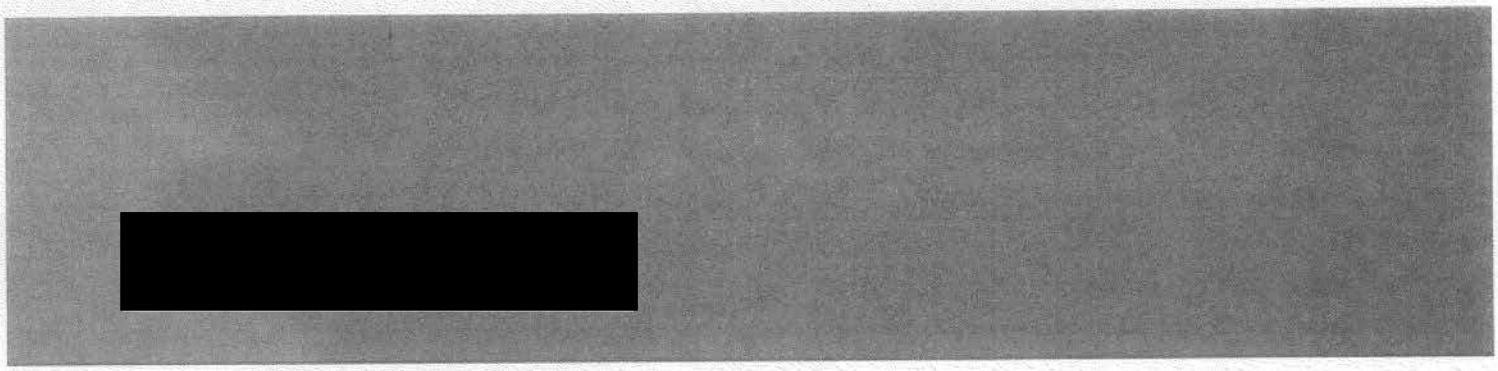

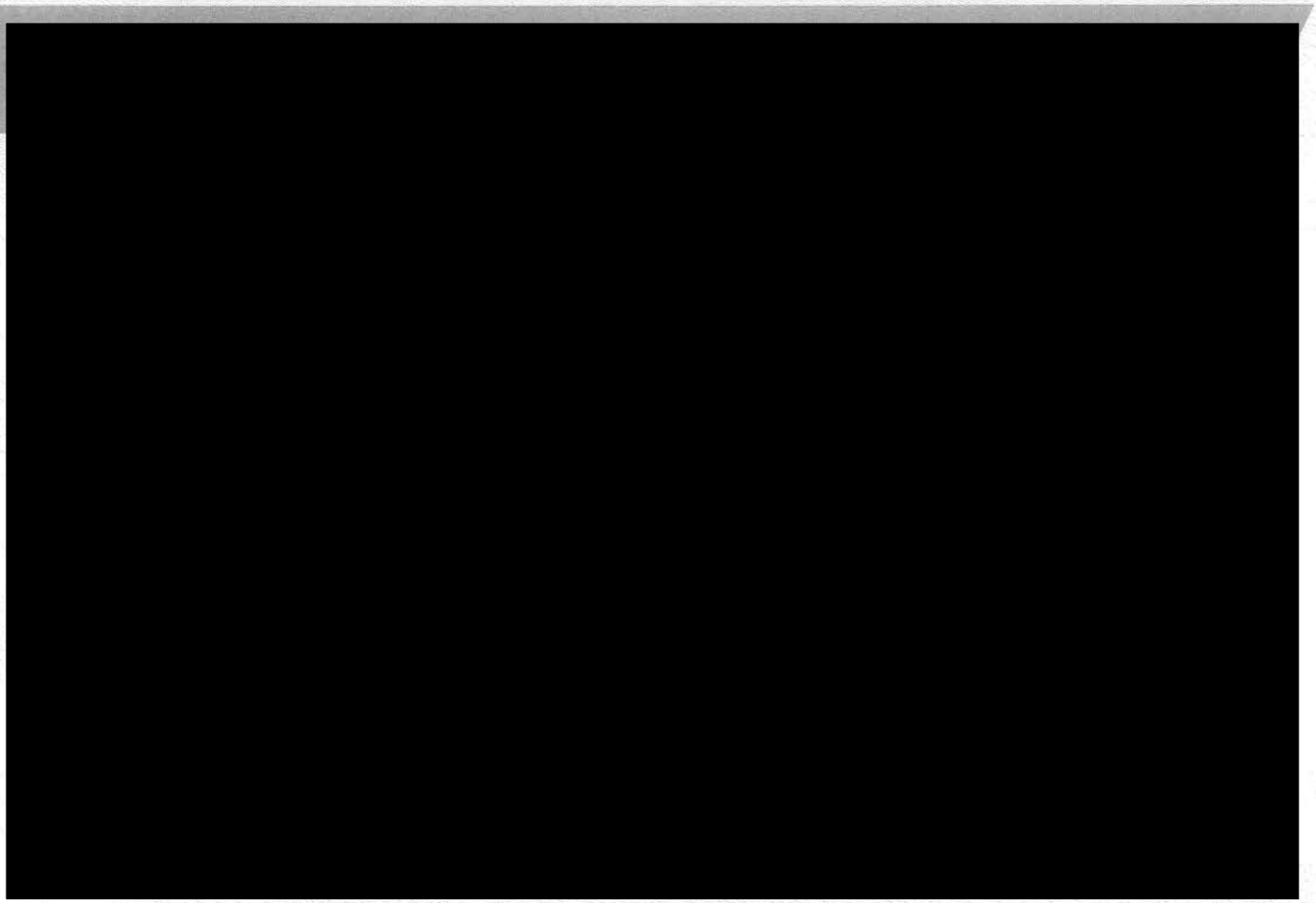

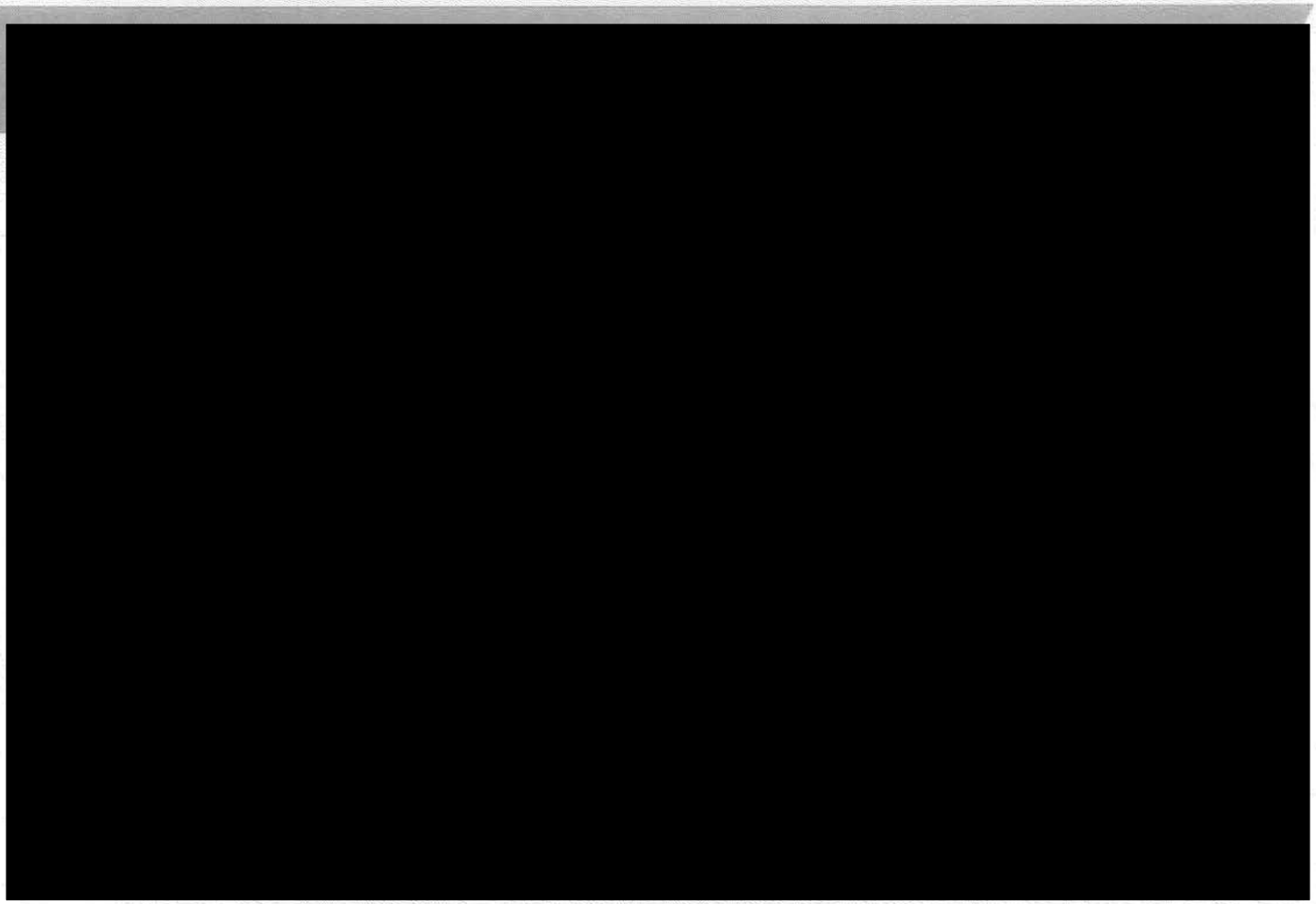

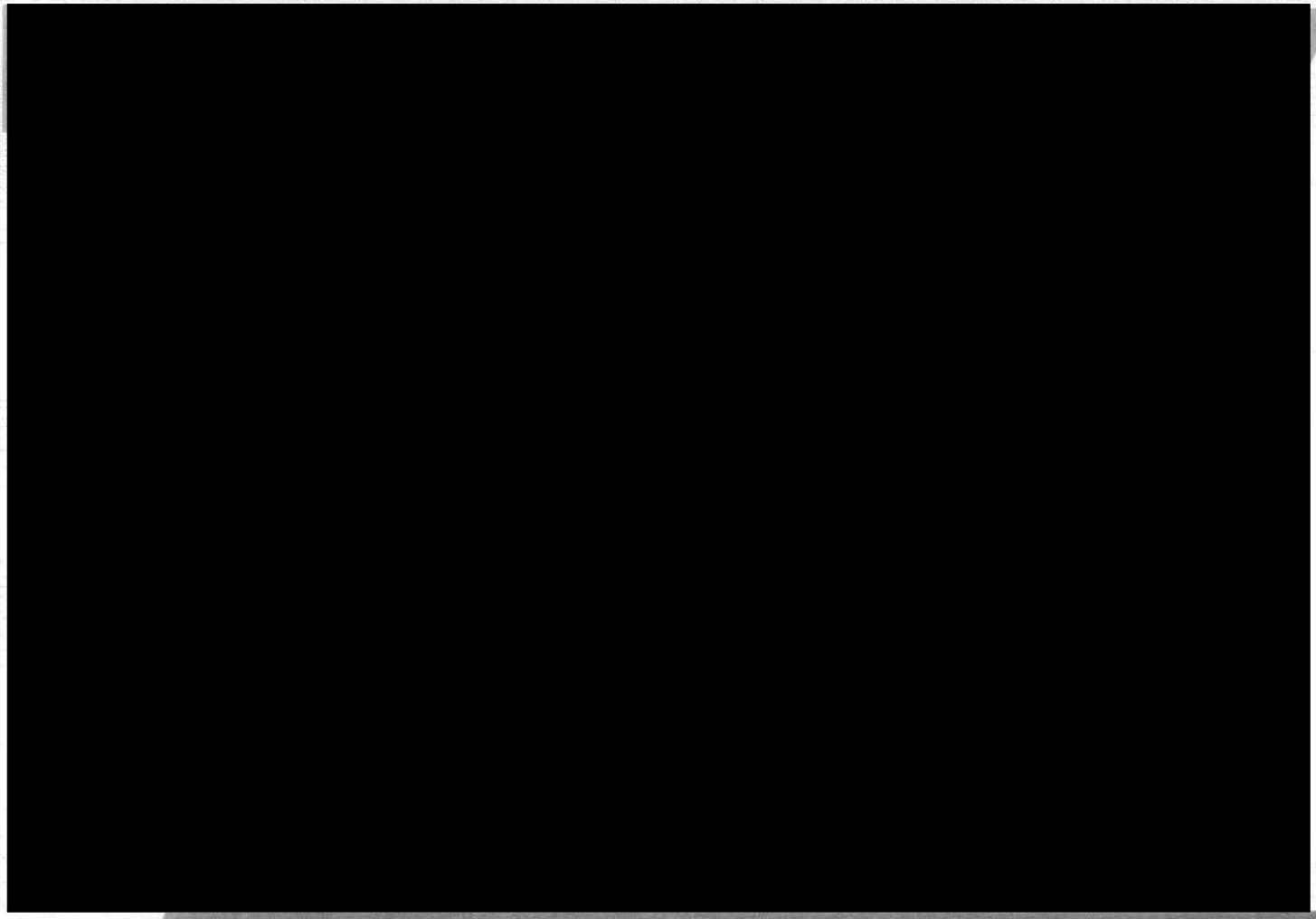

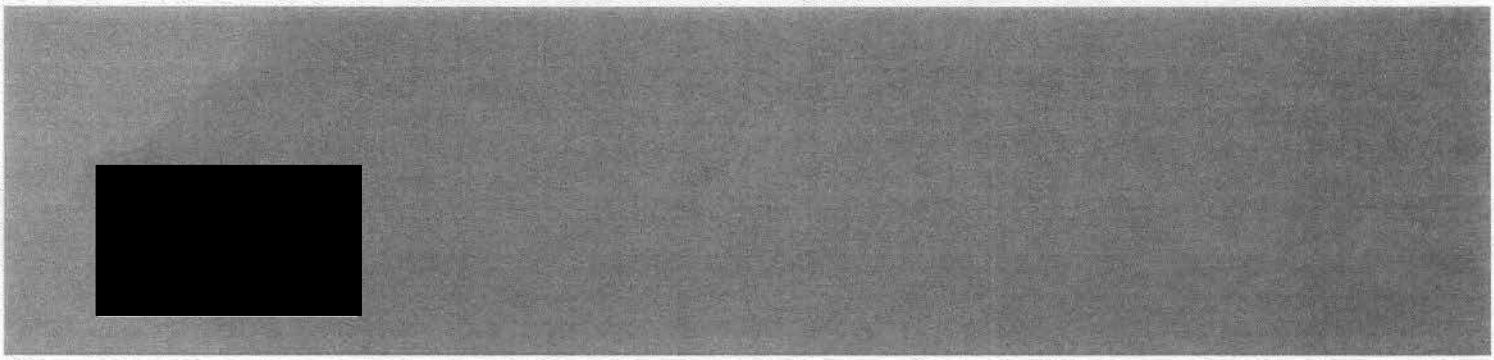

EXHIBIT 105

In the
United States Court of Appeals
For the Second Circuit

AUGUST TERM, 2014

ARGUED: APRIL 13, 2015
DECIDED: MAY 22, 2015

No. 14-4624

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,
Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,
Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of New York.
No. 14 Civ. 7473 – Robert W. Sweet, *Judge.*

Before: WALKER, RAGGI, and DRONEY, *Circuit Judges.*

The State of New York brought this antitrust action against Defendant-Appellant Actavis plc and its wholly-owned subsidiary

Forest Laboratories, LLC (collectively, "Defendants"). New York alleges that as Namenda IR, Defendants' twice-daily drug designed to treat moderate-to-severe Alzheimer's disease, neared the end of its patent exclusivity period in July 2015, Defendants introduced a new once-daily version called Namenda XR. The patents on XR ensure exclusivity, and thus prohibit generic versions of XR from entering the market, until 2029. Faced with the prospect of competition from generic IR, Defendants decided to withdraw virtually all Namenda IR from the market in order to force Alzheimer's patients who depend on Namenda IR to switch to XR before generic IR becomes available. Because generic competition depends heavily on state drug substitution laws that allow pharmacists to substitute generic IR for Namenda IR—but not for XR—New York alleges that Defendants' forced-switch scheme would likely impede generic competition for IR. Moreover, the substantial transaction costs of switching from once-daily XR back to twice-daily IR therapy would likely further ensure that Defendants

would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents.

The United States District Court for the Southern District of New York (Robert W. Sweet, *Judge*) issued a preliminary injunction barring Defendants from restricting access to Namenda IR prior to generic IR entry. We conclude that the district court did not abuse its discretion by granting New York's motion for a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its claim under the Sherman Act, 15 U.S.C. § 2, and has made a strong showing of irreparable harm to competition and consumers in the absence of a preliminary injunction. Accordingly, we affirm the district court's order issuing a preliminary injunction.

LISA S. BLATT, Arnold & Porter LLP, Washington, D.C. (Sarah M. Harris, Robert A. DeRise, Arnold & Porter, LLP, Washington, D.C.; George T. Conway III, Wachtell, Lipton, Rosen & Katz, New York, N.Y.; J. Mark Gidley, Peter J. Carney, Claire A. DeLelle, White & Case LLP, Washington, D.C.; Jack E. Pace III, Martin M. Toto, White & Case

LLP, New York, N.Y., *on the brief*), *for Defendants-Appellants.*

ANISHA S. DASGUPTA, (Barbara D. Underwood, Andrew Kent, Eric J. Stock, Elinor R. Hoffmann, *on the brief*), *for* Eric T. Schneiderman, Attorney General of the State of New York, New York, N.Y., *for Plaintiff-Appellee.*

JOHN M. WALKER, JR., *Circuit Judge*:

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injunction. Accordingly, we affirm the district court's order issuing a preliminary injunction.

BACKGROUND

This case raises a novel question of antitrust law: under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as "product hopping,"[1] violate the Sherman Act, 15 U.S.C. §§ 1 and 2. This question is an issue of first impression in the circuit courts. Determining whether Defendants' actions are unlawfully anticompetitive requires some understanding of the idiosyncratic market characteristics of the complex and highly-regulated pharmaceutical industry, as well as some peculiar characteristics of treatment for Alzheimer's disease. We begin by describing several key features of the pharmaceutical industry.

[1] The term "product hopping" was coined by Herbert Hovenkamp. *See* Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 Mich. St. L. Rev. 631, 658 (2007) (citing Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principals Applied to Intellectual Property Law* (2002)).

I. FDA Requirements, the Hatch-Waxman Act, and State Drug Substitution Laws

In compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f, when a pharmaceutical manufacturer seeks to bring a new drug to market, it must submit a New Drug Application ("NDA") for approval by the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 355. An NDA must contain scientific evidence that demonstrates the drug is safe and effective, which inevitably requires "a long, comprehensive, and costly testing process." *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). NDA-approved drugs are generally referred to as brand-name or brand drugs. An approved brand drug enjoys a period of patent exclusivity in the market at the end of which one or more generic drugs,[2] exhibiting the same characteristics as the brand drug, may enter the market at a lower price to compete with the brand drug.

In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by enacting the Drug Price Competition and Patent

[2] Generic drugs "are copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." FDA, *Understanding Generic Drugs*, http://1.usa.gov/1SjEIso (last visited Apr. 14, 2015).

Term Restoration Act (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585. Hatch-Waxman was designed to serve the dual purposes of both encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate through patent extensions. To incentivize innovation, Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and an additional six-month period of "pediatric exclusivity" if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a. Defendants applied for, and received, both extensions for Namenda IR.

Hatch-Waxman also promotes competition from generic substitute drugs. It permits a manufacturer that seeks to market a generic version of an NDA-approved drug to file what is known as an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C.

§ 355(j); *see also In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 130 (2d Cir. 2014). An ANDA allows a generic manufacturer to rely on the studies submitted in connection with the already-approved brand drug's NDA to show that the generic is safe and effective, provided that the ANDA certifies that the generic drug has the same active ingredients as and is "biologically equivalent" or "bioequivalent" to the already-approved drug.[3] 21 U.S.C. § 355(j)(2)(A)(iv); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)).

A generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as that of the brand drug. 21 U.S.C. § 355(j)(8)(B)(i). In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time. By enabling generic manufacturers to "piggy-back" on a brand drug's scientific studies, Hatch-Waxman "speeds the introduction of low-cost generic drugs to market, thereby

[3] An ANDA also requires a manufacturer to demonstrate other measures of equivalence between the brand and generic drugs, which are not relevant here. 21 U.S.C. § 355(j)(2)(A).

furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (internal quotation marks, alteration, and citation omitted); *see also* H.R. Rep. No. 98-857, pt. 2, at 9 (1984) (stating the Hatch-Waxman Act's "policy objective" was to "get[] safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent").

By the time Congress enacted the Hatch-Waxman Act, many states had enacted drug substitution laws to further encourage generic competition.[4] Today, all 50 states and the District of Columbia have drug substitution laws.[5] Although the specific terms of these laws vary by state, drug substitution laws either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be

[4] *See* Alison Mason & Robert L. Steiner, Fed. Trade Comm'n, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 1 (1985), *available at* http://1.usa.gov/1IS44Ju ("FTC, *Generic Substitution*").

[5] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1009, 1017 (2010) ("Carrier, *A Real-World Analysis*"); *see also* Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 Colum. L. Rev. 1471, 1479-80 (2008) ("Cheng, *Product Hopping*").

dispensed as written.[6] For example, New York's drug substitution law requires a pharmacist to "substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed" provided certain conditions are met. N.Y. Educ. Law § 6816-a(1).

All state drug substitution laws prohibit pharmacists from substituting generic drugs that are not therapeutically equivalent to the brand drug, but state laws do not all define therapeutic equivalence in the same way.[7] Thirty states, including New York and the District of Columbia, adopt the FDA's definition of therapeutically equivalent and only allow generic substitution if the FDA designates the generic as "AB-rated" in a publication commonly referred to as the "Orange Book."[8] N.Y. Education Law

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[6] The FTC, like the district court, has found that only a "modest[]" difference in the frequency of substitution rates exists between states with mandatory substitution laws and states with permissive substitution laws. *See* FTC, *Generic Substitution*, at 99.

[7] *See* Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist (June 19, 2008), http://www.uspharmacist.com/content/s/44/c/9787; *see also* FTC, *Generic Substitution*, at 3 (Vivian, *Generic-Substitution Laws*).

[8] Some states explicitly require generic drugs to have an AB-rating, some states adopt the requirements of an AB-rating without using the term, some states develop formularies that list permissible or impermissible drug substitutes, and some states give discretion to individual pharmacists as long as

§ 6816-a(1); N.Y. Public Health Law § 206(1)(o). To receive an AB-rating, a generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug, meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug. U.S. Dep't of Health & Human Servs., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* vii-x (35th ed. 2015), *available at* http://1.usa.gov/1PzbMxF (the "Orange Book"). The AB-rating requirement is designed to provide guidance regarding which drugs are therapeutically equivalent, but, as has been observed, it also provides an opportunity for brand manufacturers to "game" the system.[9] S.A. 28.

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the drugs are pharmaceutically equivalent. *See* Vivian, *Generic-Substitution Laws* tbl.2.

[9] *See, e.g.*, Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 709 (2009) (explaining that the regulatory framework that governs the pharmaceutical industry "presents a perfect storm for regulatory gaming"); Cheng, *Product Hopping*, at 1494 ("Product hopping itself amounts to little more than a thinly disguised scheme to game the pharmaceutical industry's regulatory system."); Intellectual Property and Antitrust Professors *Amicus* Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 3 (explaining that product hopping "presents a paradigmatic case of a regulatory game. . . . [It] exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing competition" (alterations in original)); American Antitrust Institute *Amicus* Brief in Support of Appellee ("AAI Br.") at 6, 10-11 (explaining that branded manufacturers can game the system by changing the form of the brand product before generics enter the market).

Hatch-Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account. *See* American Antitrust Institute *Amicus* Brief in Support of Appellee ("AAI Br.") at 6; *see also* Intellectual Property and Antitrust Professors *Amicus* Brief in Support of Appellee ("IP and Antitrust Prof. Br.") at 12. As the Federal Trade Commission has explained,

> [t]he basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in

> determining which products they will buy and what prices they must pay for prescription.

Fed. Trade Comm'n Bureau of Consumer Prot., *Drug Product Selection* 2-3 (1979), *available at* http://bit.ly/1JqKd4G. ("FTC, Drug Product Selection"). State substitution laws are designed to correct for this price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to pharmacists and patients, who have greater financial incentives to make price comparisons.[10] *See* AAI Br. at 8-9.

II. The Relevant Market

The relevant market, undisputed on appeal, is the memantine-drug market in the United States. Defendants manufacture Namenda, a memantine hydrochloride-based[11] ("memantine") drug

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[10] Perhaps counter-intuitively, pharmacists have an incentive to dispense lower-cost generic drugs because pharmacies typically realize higher profit margins on generic drugs due to health plan incentives. *See* Antitrust Economists *Amicus* Brief in Support of Appellants ("Antitrust Economists Br.") at 12; *see also* Carrier, *A Real-World Analysis*, at 1017 ("[State drug product selection] laws carve out a role for pharmacists, who are much more sensitive to prices than doctors.").

[11] Memantine is an N-Methyl D-Aspartate ("NMDA") receptor antagonist that affects the glutamate pathway in the brain. As expert Dr. Alan Jacobs, a neurologist in private practice, explained at the preliminary injunction hearing:

> Neurons in the brain communicate by signaling each other. Some of these signals are transmitted through an influx of calcium into a

designed to treat moderate-to-severe Alzheimer's disease. Namenda is currently available in two formulations: a twice-daily immediate-release drug, Namenda IR, and a once-daily extended-release drug, Namenda XR. When Forest introduced Namenda IR tablets in January 2004, Namenda IR was the first medication approved for individuals suffering from moderate-to-severe Alzheimer's disease.[12] Namenda IR became one of Forest's best-selling drugs—generating approximately $1.5 billion in annual sales in 2012 and 2013. The FDA approved Namenda XR in June 2010,

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> molecule on the surface of neurons called the NMDA receptor. This influx of calcium is triggered when glutamate, an excitatory neurotransmitter, docks at the NMDA receptor, causing the calcium influx. When patients enter the moderate stage of Alzheimer's disease, there can be overexcitation of the NMDA receptor by glutamate.

S.A. 16. Memantine-based drugs, like Namenda, partially block the brain's NMDA receptor in order to prevent "overexcitation" of that receptor, "which can cause toxicity to neurons in the brain." S.A. 17.

In contrast, the three other FDA-approved drugs on the market to treat Alzheimer's disease—Aricept, Exelon, and Razadyne—are all acetylcholinesterase inhibitors ("CIs"). CIs reduce the breakdown of acetylcholine, a chemical messenger that transmits information between nerve cells, in the brain. Rather than work on the glutamate pathway, like Namenda, CIs work on the acetylcholine pathway. CIs are generally prescribed to patients experiencing the early stage of Alzheimer's disease, and are prescribed in conjunction with—but not independently of—Namenda during the moderate-to-severe stages of Alzheimer's disease.

[12] Defendants also introduced a twice-daily liquid version of Namenda IR in 2005.

and Forest began marketing XR in 2013. The two drugs are the only memantine therapies in their class—N-Methyl D-Aspartate ("NMDA") receptor antagonists—currently on the market.[13]

Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect. The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.[14] All other Alzheimer's disease treatments are administered once a day.

The non-medical difference between IR and XR relates to their patent protection. Defendants' patents on Namenda IR prohibit any manufacturer from marketing a generic version of IR until July 11, 2015 (Namenda IR's "exclusivity period").[15] The exclusivity period

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[13] Because CIs perform different functions, Aricept, Exelon, and Razadyne are not substitutes for Namenda.

[14] Additionally, Namenda IR and Namenda XR have different dosage forms. J.A. 673 n.57. Namenda IR is marketed in tablet form, whereas Namenda XR is marketed in capsule form. *Id.*; *see also Dosing for Patients Currently Taking NAMENDA*, http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx (last visited Apr. 16, 2014).

[15] Defendants' patents on Namenda IR prohibit generic entry until October 2015. But in 2009 and 2010, in order to resolve patent litigation, Forest entered into licensing agreements permitting ten generic competitors to enter the market three months before Namenda IR's official exclusivity period ends.

for Namenda XR does not expire until 2029. A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the "patent cliff."

III. Defendants' Introduction of Namenda XR and Withdrawal of Namenda IR

Namenda IR and Namenda XR currently occupy the entire memantine-drug market. However, five generic versions of IR have tentative FDA approval to enter the market on July 11, 2015, and seven others may enter the market as early as October 2015. Because Namenda XR has a different strength and daily dosage regimen—Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28mg extended-release capsule[16]—the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to

[16] *See Dosing for Patients Currently Taking NAMENDA*, Namenda XR, http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx (last visited Apr. 16, 2014).

Namenda IR, but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.

When Defendants brought Namenda XR to market in July 2013 (approximately three years after it was approved), they adopted so-called "product extension" strategies to convert patients from Namenda IR to Namenda XR and, thus, to avoid the patent cliff. Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent approximately $120 million promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it up to 20% less expensive than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR. The parties have referred to Defendants' efforts to transition patients to XR while IR was still on the market as the "soft switch," and we will adopt that term.

In early 2014, Defendants decided on a more direct approach. They were concerned that they would be unable to convert a significant percentage of Alzheimer's patients dependent upon memantine therapy from IR to XR prior to the entry of generic IR. Defendants' internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015. On February 14, 2014, Defendants publicly announced that they would discontinue Namenda IR on August 15, 2014, notified the FDA of their plans to discontinue Namenda IR, and published letters on their websites urging caregivers and healthcare providers to "discuss switching to Namenda XR" with their patients. S.A. 51-52. Defendants also sought to convert Namenda IR's largest customer base, Medicare patients, to XR by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it. Their planned discontinuance was delayed by a disruption in XR production, and in June 2014, Defendants announced that Namenda IR would be available until the fall of that year.

But before Defendants withdrew IR entirely, intervening events again prompted them to modify their plans. In September 2014, New York State filed a complaint alleging that Defendants' planned withdrawal of Namenda IR violated the antitrust laws. Defendants subsequently entered into an agreement with Foundation Care, a mail-order-only pharmacy, to provide for limited access to Namenda IR if medically required. Under the terms of the agreement, Foundation Care is authorized to dispense Namenda IR tablets only after receiving a form from a doctor stating that it is "medically necessary" for the patient to take Namenda IR. Defendants estimated internally that less than 3% of current Namenda IR users would be able to obtain IR through Foundation Care. S.A. 67. Although the agreement with Foundation Care makes IR available to a limited number of patients, Defendants' actions effectively withdrew Namenda IR from the market. The parties have referred to Defendants' efforts to withdraw Namenda IR from the market as the "hard switch" or "forced switch," terms we also adopt. The hard switch began on February 14, 2014 with the

announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

IV. Procedural History

In September 2014, New York State filed a complaint in the District Court for the Southern District of New York (Robert W. Sweet, *Judge*) alleging that Defendants were violating the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, as well as New York's Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.*, and seeking a permanent injunction and damages. New York also sought a preliminary injunction barring Defendants from restricting access to Namenda IR during the course of the litigation.

New York's theory of antitrust liability, in substance, is as follows. As Namenda IR neared the end of its exclusivity period, Defendants introduced Namenda XR and, before generic IR was

available, withdrew Namenda IR in order to force patients to switch from IR to XR (for which generic IR will not be substitutable under most states' laws). In doing so, Defendants intended to thwart generic entry into and competition in the memantine-drug market in order to maintain their monopoly in that market.

The district court held a five-day hearing on the preliminary-injunction motion, during which it received testimony from 24 witnesses and reviewed over 1,400 exhibits. After considering that evidence, the district court made several key findings. (1) Withdrawing Namenda IR from the market prior to generic entry forces Alzheimer's patients dependent on memantine therapy to switch to Namenda XR because it is the only available alternative; (2) The generic versions of IR poised to enter the market in July and October of 2015 will not be AB-rated to XR because they have different strengths and dosages; (3) Pharmacists will not be permitted to substitute generic IR for Namenda XR under New York and many other states' substitution laws because generic IR is not therapeutically equivalent to Namenda XR; (4) If Defendants forced

Alzheimer's patients to switch to Namenda XR prior to generic entry, those patients would be very unlikely to switch back to twice-daily IR therapy even after less-expensive generic IR becomes available, due to the high transaction costs associated with Alzheimer's patients first switching from one formulation of a drug to a new formulation and then back to the original formulation ("reverse commuting"); (5) Preventing generic IR from competing under state drug substitution laws would likely thwart generic entry into and competition in the memantine-drug market; and (6) In withdrawing Namenda IR from the market, Defendants' explicit purpose was to impede generic competition and to avoid the patent cliff—which occurs at the end of a drug's exclusivity period when generics gain market share through state substitution laws.

Based on those findings, the district court granted New York's request for a preliminary injunction. The district court concluded that New York raised serious questions regarding the merits of its claims under Sections 1 and 2 of the Sherman Act and the Donnelly Act, demonstrated the potential for irreparable harm, and concluded